



Multi-stakeholder platform Proposed model for 2023/2024

Multi-stakeholder platform kick-off meeting
22-23 June 2023



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An agency of the European Union



In this presentation

1. Why do we need a multi-stakeholder platform for clinical trials?
2. Objectives of the multistakeholder platform
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Why do we need a multi-stakeholder platform?

The CTR intensifies the need for dialogue among stakeholders

COVID-19 pandemic highlights need for more multinational clinical trials

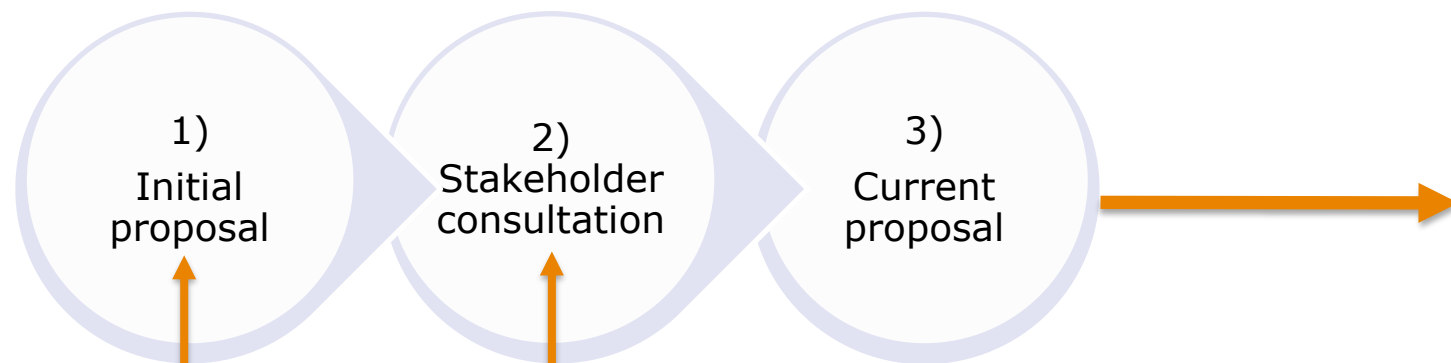
There is an absence of structured forum & process to build consensus for change

To evolve with advances in regulation, methodologies, technology, science, we need multi-stakeholder discussions

Objectives

Accelerate change	and innovation in how clinical trials are regulated, designed, conducted & evaluated
Connect stakeholders	in a neutral forum for regular, and balanced discussions
Build trust	by understanding different perspectives, opening avenues for change
Drive transparency	and sharing of discussion outcomes

Journey so far



ACT EU Steering Group

ACT EU MSP plenary meetings main activities:

- Identification and prioritisation of workplan topics
- Presentation of the workplan topics and call for *ad hoc* topic groups volunteers
- Discussion of proposals and pilot projects for clinical trial improvement
- Progress report to ACT EU SG

Ad hoc topic groups main activities

- Coordinate meetings, work and pilots
- Record work and decisions
- Draft proposals
- Present updates/proposals to MSP plenaries

Positive feedback with some risks & concerns identified

- Loss or regulatory oversight/compliance with legal obligations
- Composition/level of expertise to enable right stakeholder engagement
- Resourcing constraints
- Parallel discussion of same topics by different groups

Guiding principles for the MSP development

1. Start small and evolve based on experience
2. Travel together and be advised by stakeholders
3. Acknowledge the problems we face and remain focused on benefits



ACT EU Steering Group

We are missing the strategic link between ACT EU and our stakeholder communities



Priority actions deliver work of ACT EU

Stakeholders support ACT EU on an *ad hoc* basis including workshops/consultations.

ACT EU Priority actions



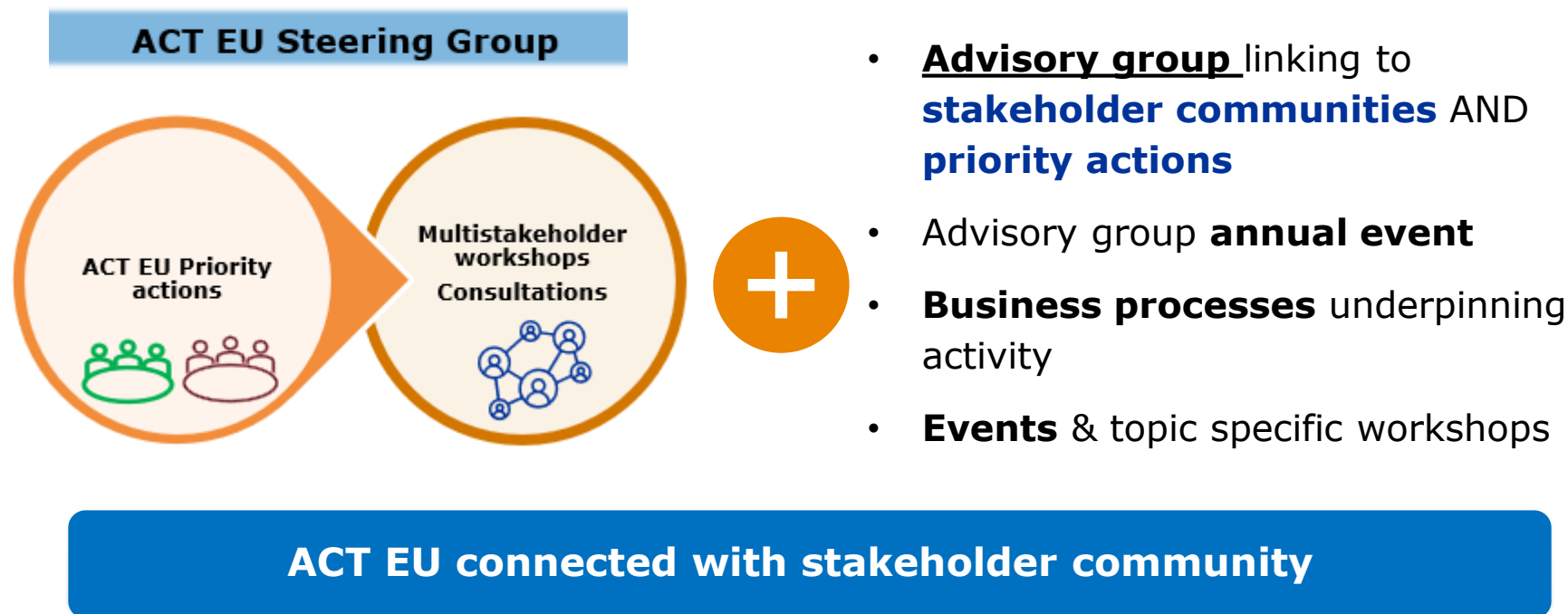
Multistakeholder workshops
Consultations
Surveys etc



Stakeholder communities

Academics as CT data users | CRO | Clinical trial investigators | Ethics committee members | Healthcare Professionals | HTA bodies | Inspectorates | Patients | Payers | Policy makers | Regulators | Research funders | Sponsors (commercial sponsors academia and SMEs)

Integrate MSP (elements) with existing programme structure

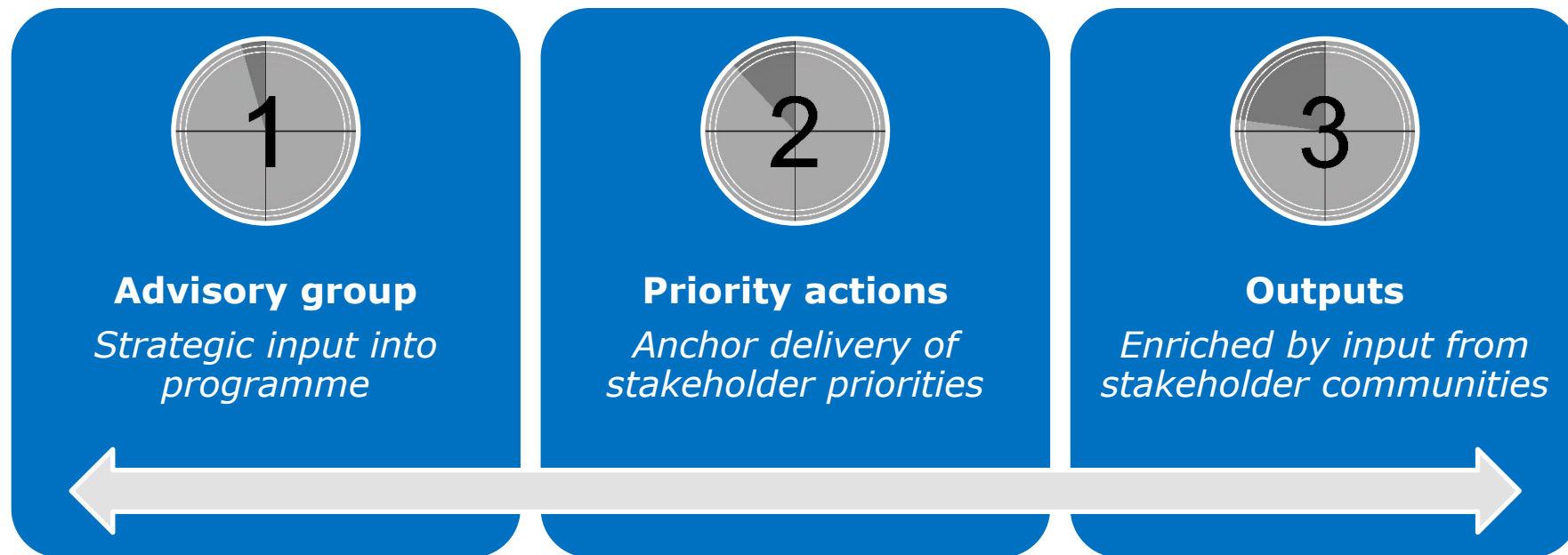


Advisory group

- Will contribute strategically to the ACT EU programme.
- Will include representation from all stakeholder groups & ACT EU enabling bidirectional exchange.
- Will identify stakeholder priorities and advise on best method for contribution.
- Will facilitate creation of topic specific workshops (technical discussions) and review groups for PAs (if needed).
- Will advise on stakeholder engagement and communication.



In conclusion..



What happens now?

1. Listen and discuss:

What are the key features for a MSP platform?

If there is broad agreement to proceed:

1. Define selection criteria for Advisory Group representation
2. Call for nominations
3. Draft mandate and rules of procedure for Advisory Group

